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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,901	04/23/2007	Darrell H. Reneker	089498.0500.US	7722

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EXAMINER	
COLELLO, ERIN L	

ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,901	RENEKER ET AL.	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed May 23, 2011. Claims 1-5 and 16 are pending and an action on the merits is as follows.

Applicant's arguments filed May 23, 2011 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-5 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lau et al. (US 5,876,432).**

Regarding claim 1, Lau discloses a stent comprising: a stent member (Ref 220; Column 24, Lines 55-67); a release layer, wherein the stent member is coated with the release layer (Ref 224; Column 17, Lines 58-67; Column 18, Lines 19-35; Column 23, Lines 37-47; Column 24, Lines 55-67; wherein the tubular component is a layer that is spread over the inner surface of the stent and therefore the stent is coated with the tubular component layer); and an insoluble fibrous component, wherein the insoluble fibrous component is wrapped around the stent (Ref 222; Column 8, Lines 55-63; Column 9, Lines 34-41; Column 14, Lines 55-67; Column 15, Lines 1-31; Column 24, Lines 55-67; Column 25, Lines 1-14; wherein the fibers can be placed around the stent

and therefore wrap around the stent), wherein the insoluble fibrous component forms a reinforcing thrombus plug upon degradation of the release layer (Column 15, Lines 1-61; wherein the insoluble fibrous component helps reinforce the vessel wall and isolate aneurysms and is therefore forming a thrombus plug that isolates aneurysms), and wherein the insoluble fibrous component is secured in place during implantation by the release layer (Column 24, line 55- Column 25, line 14 and 38-53; wherein the insoluble fibrous component can be imbedded within the release layer and is therefore secured in place by the release layer), the release layer being designed to degrade only after implantation of the stent is complete (Column 23, lines 30-47; wherein the release layer can be used as a temporary repair unit and can degrade under physiological conditions and wherein the release rate can be adjusted by varying the chemical structure of the release layer).

Regarding claim 3, Lau discloses that the insoluble fibrous component comprises a compound selected from poly(caprolactone), polyethylene terephthalate, fibrinogen, polyolefins, polyethylene, polypropylene, linear poly(ethylenimine), cellulose acetate, grafted cellulosics, poly (L-lactic acid), poly (ethyleneoxide), poly (hydroxyethylmethacrylate), poly (glycolic acid), poly vinylpyrrolidone, polyethylene glycol, polyethylene oxazoline, polyester, polyacrylic acid, polyacrylic acid esters, polyphosphezines, polycyanoacrylate, polyvinyl amines, polyethylene imines, polyethylene amines, polyacrylamides, cellulose, polyorthoesters, polyanhydrides, polyketals, polyacetals, polyureas, and polycarbonate (Column 14, Lines 55-67; Column 15, Lines 1-31; Column 25, Lines 1-14).

Regarding claim 4, Lau discloses that the insoluble fibrous component comprises Dacron (Column 25, Lines 1-14; wherein Extrinsic Evidence Rhodes (5,665,117) teaches that Dacron is a thrombogenic and fibrogenic material that initiates the formation of a thrombus in order to stimulate the incorporation of the prosthesis by fibrosis to the vessel wall in order to ensure a complete and permanent seal and prevent rupture of an aneurysm (Column 7, lines 7-36)).

Regarding claim 5, Lau discloses that the thrombogenic material at least partially blocks the entrance to a structure selected from the group consisting of an aneurysm, a fistula, and an opening in a blood vessel wall (Column 15, Lines 1-61; wherein the stent helps reinforce the vessel wall and isolate aneurysms).

Regarding claim 16, Lau discloses a method for using the stent of claim 1, the method comprising the step of implanting the stent in a living organism (Figures 14A-C; Figures 15A-C; Column 26, Lines 24-49.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lau et al. (US 5,876,432).**

Regarding claim 2, Lau discloses that the insoluble fibrous component comprises a small fiber but fails to explicitly disclose that it is a nanofiber

However, it would have been an obvious matter of design choice to make the fiber a nanofiber, since it has been held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984).

Response to Arguments

Applicant's arguments filed May 23, 2011 have been fully considered but they are not persuasive.

- Applicant argues that the fibrous component is inside the stent and is therefore not wrapped around the stent

  The Examiner respectfully disagrees. The claim language merely states that the fibrous component has to be wrapped around the stent and **there is nothing in the claim language that precludes the fibrous component from being inside the stent**. Therefore, since Lau discloses a fibrous component that is wrapped around the inside of the stent, the device of Lau meets the claim language and the arguments are not persuasive.

- Applicant argues that Lau cannot teach a reinforcing thrombus plug since the fibrous layer of Lau is within the stent.

  The Examiner respectfully disagrees. The claim language merely states that the fibrous layer is wrapped around the stent and forms a reinforcing thrombus plug and **there is nothing in the claim language that precludes the fibrous**

component from being inside the stent or that further defines how the fibrous layer forms a reinforcing thrombus plug. Therefore, since Lau discloses a fibrous component that is wrapped around the inside of the stent and helps reinforce the stent and vessel wall and helps isolate/plug the aneurysm, the device of Lau can be interpreted as forming a thrombus plug that isolates aneurysms and therefore the arguments are not persuasive.

- Applicant argues that Lau doesn't teach a release (middle) layer that is between the stent and the (outer) fibrous layer.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a middle release layer that is between the stent and the outer fibrous layer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Examiner additionally notes that claim 1 is claiming a stent member, a release layer and an insoluble fibrous component that is wrapped around the stent and Lau teaches a stent member (220), a release layer (224; C23, L30-47;C24, L55-C25, L14; C25, L38-53) and an insoluble fibrous component that is wrapped around the inside of the stent (222) and therefore the arguments are not persuasive.

- Applicant argues that Lau doesn't teach a release layer that degrades only after implantation, since Lau teaches that element 224 is a tubular component.

The Examiner respectfully disagrees, Lau discloses that element 224 (the release layer) can be used as a temporary repair unit and can degrade under physiological conditions and that the release rate can be adjusted by varying the chemical structure of the release layer (Column 23, lines 30-47). Since Lau not only discloses that 224 is a tubular component, which can be interpreted as a layer on the stent but additionally discloses that the release layer 224 can degrade under the physiological conditions that occur when the stent is implanted within the body and that the release rate can be adjusted as desired, the arguments are not persuasive.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-

3212. The examiner can normally be reached on Monday-Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at* (571) 272-4697**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov**.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3734